REMARKS

The above-identified application has been carefully reviewed with the Office Action of June 10, 2010, the Examiner's comments, and the prior art references cited therein in mind. In response thereto, the Applicant has amended the specification, the drawings, and claims 1, 3-5, 7, 14, 17, 19-21, 23, 30, and 32. In addition, the Applicant submits the following arguments in support of patentability. Favorable reconsideration is hereby respectfully requested.

The drawings have been objected to under 37 C.F.R. 1.84(p)(4). Corrected drawings in compliance with 37 C.F.R. 1.121(d) are submitted herewith along with amendments to the specification to correspond to the drawing changes. Thus, the drawings and the specification are now believed to be in proper form.

Claims 1-5, 9-10, 13-14, 17-21, 25-26, 29-31, and 33 have been rejected under 35 U.S.C. §102(b) as being anticipated by Garren et al (U.S. Patent No. 4,899,747). The Office Action opines that Garren et al discloses a kit for introducing a surgical implant into a cavity in the body of a patient, the kit having a surgical implant for implanting in the cavity, the implant being expandable from the configuration for introduction to a therapeutic configuration within the cavity, and a cartridge for packaging the implant in the introduction configuration. The cartridge is provided with an opener member, attributing this element to the free end of the drawstring. The opening member is activatable by positive action enabling the cartridge to pass from a closed configuration to an expanded configuration. The cartridge includes locking means functionally connected to the opener member and capable on its own without any external action on the locking means of holding the cartridge in the closed configuration. The drawstring of Garren et al has been interpreted as the locking means, the proximal free end is interpreted as the opener member and the zigzag configuration of the drawstring is said to allow the drawstring to maintain the cartridge in the closed configuration without any external action. The Applicant respectfully disagrees with this reading of Garren et al.

A proper rejection of a claim under 35 U.S.C. §102 requires that a single prior art reference disclose each element of the claim. *See, e.g., W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983). Anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. *See e.g., In re Paulsen,* 30 F.3d 1475, 31 USPQ 2d 1671 (Fed. Cir. 1994); *In re Spada*, 911 F.2d 705, 15 USPQ 2d 1655 (Fed. Cir. 1990).

The present application has claims directed to a kit for introducing a gastric implant into the stomach (claim 1), a cartridge for introducing an intragastric implant into the stomach, the

cartridge holding the implant prior to its introduction (claim 17), and a method of manufacturing a kit for introducing an intragastric implant into the stomach, detailing the steps of introducing the implant in a cartridge, opening the cartridge and allowing the implant to expand (claim 30). These are the independent claims currently pending in the application. While they are all distinctive on their own, they can be addressed together in the remarks as the amendments made to each of the independent claims are somewhat similar. In addition, the distinction between each of the independent claims and the Garren et al reference includes some similarities as well.

The kit includes an intragastric implant having a first configuration for introduction into the stomach and an expanded configuration, achievable after implantation in order to reduce the volume of the stomach. The cartridge includes an opener member activatable by positive action to essentially open the cartridge and allow the implant to expand. The cartridge includes locking means functionally connected to the opener member and capable on its own, without requiring any external action on the locking means of holding the cartridge in the closed configuration. The cartridge further comprises a sleeve provided with at least one side opening formed along its length, the opening being closed by the locking means when the cartridge is in the closed configuration and the opening being disengaged to allow the implant to expand when the cartridge is in the open configuration. The method claim, claim 30, teaches a method of manufacturing a kit for introducing an intragastric implant into the stomach of a patient, the method comprising the steps of supplying the intragastric implant; supplying a cartridge for packaging the implant in the introduction configuration; providing the cartridge with an opener member activatable by positive action enabling the cartridge to pass form a closed configuration to an open configuration; and, locking the cartridge in the closed configuration, the locking means capable on its own without requiring any external action on the locking means of holding the cartridge in the closed configuration and locking the cartridge in substantially the shape of a sleeve, the sleeve including at least one axial opening at one of the ends of the sleeve.

Garren et al disclose a different device. Garren et al is discussed in the prior art section of the present application on page 4. The Garren et al device can be deployed in two ways. The first deployment involves pushing the intragastric implant 10 out of the stomach tube 20, using the insufflation tube 22. In a second embodiment, shown in Figs. 9-11 and discussed in Cols. 4 and 5 of the Garren et al reference, Garren et al teaches to use a stomach tube 20a with a longitudinal slit 32 extending from the inner end thereof upwardly a short distance about 2 to 5 inches. The slit in the tube is closed by a drawstring threaded through loops in zigzag fashion from the end of the tube upwardly and into the interior of the tube at the opposite end.

The drawstring extends through the tube to the outer free end thereof, and when tensioned, it closes the tube at the slit. (Col. 5, lines 7-9) As can be seen in Fig. 10 of the Garren et al reference, several redundant loops of the thread are formed at the distal end of the tube so that an initial traction force on the free end of the thread enables the slit to be closed but which; however, must be loose enough whereby the string may be withdrawn from the loops when slightly more tension is applied. Once the string has been withdrawn, air or other fluid is introduced into the balloon via the insufflation tube to force apart the stomach tube at the slit, as shown in Fig. 11. When the balloon is fully inflated, the insufflation tube is pulled out of the balloon. The inflated size of the balloon is said to prevent the balloon from being drawn into the tube and that once the insufflation tube is detached, both it and the stomach tube are removed.

This system is different from the Applicant's device as presently claimed. The Applicant's device includes a cartridge including locking means functionally connected to an opener member and capable on its own, without requiring any external action on the locking means of holding the cartridge in the closed configuration. The cartridge further comprises a sleeve provided with at least one side opening formed along its length, the opening being closed by the locking means when the cartridge is in the closed configuration, and the opening being disengaged to allow the implant to expand when the cartridge is in the open configuration.

Garren et al, on the other hand, teaches that the slit is closed only by exerting a certain amount of tension on the thread which tension needs to be maintained all along the path followed by the balloon from the mouth to the stomach. If too much tension is applied to the string while it is being introduced, the string could be pulled out as it is designed to be removed in such a manner. Thus, Garren et al requires that the slit in the stomach tube be maintained in a locked position by exerting tension on the string. This problem has been solved by the Applicant. As discussed in the application on page 12, lines 23-26, the locking means 4, lock the cartridge to a closed configuration without any external action for maintaining the locking being required, for example, no tensioning is required.

An additional difference, detailed in amended claims 1, 17, and 30, teaches a sleeve with a side opening formed along the length of the sleeve, as opposed to the partial slit of Garren et al. Garren et al utilizes the configuration of the partial slit to assist in disengaging the balloon from the insufflation tube, thus modification of Garren et al is not an option.

Therefore, claim 1 is believed to be in condition for allowance as Garren et al does not have locking means functionally connected to the opener member and capable on its own without requiring any external action on the locking means of holding the cartridge in the closed

configuration. In contrast, Garren et al must have tension on the drawstring in order to keep the slit closed. Garren et al also does not have a sleeve provided with a side opening formed along its length. Garren et al discloses only a partial slit in the stomach tube, with the upper portion of the stomach tube being fully and permanently closed. Thus, the rejection of claim 1 and the claims dependent thereon can be withdrawn. The dependent claims are allowable for at least the reason that the independent claim 1, from which they depend, is allowable and the dependent claims are allowable as a matter of law.

Essentially the same arguments presented above with regard to claim 1 and its dependent claims, are applicable to independent claim 17. Claim 17 discloses a cartridge for introducing an intragastric implant into the stomach. The cartridge has locking means functionally connected to the opener member and capable on its own without any external action on the opening means of holding the cartridge in the closed configuration. The cartridge further comprises a sleeve provided with at least one side opening formed in its length, the side opening being closed by the locking means when the cartridge is in the closed configuration and the opening being disengaged to allow the surgical implant to expand when the cartridge is in the open configuration. As noted above, this structure is different from Garren et al and the rejection of claim 17 and the claims dependent thereon can now be withdrawn.

As discussed hereinabove, essentially the same arguments presented above with regard to claim 1 and claim 17 are applicable in part to independent claim 30. Claim 30 teaches a method for manufacturing a kit for introducing an intragastric implant into the stomach of a patient, the intragastric implant being packaged in a cartridge for introduction, the cartridge having locking means capable on its own without requiring any external action on the locking means of holding the cartridge in the closed configuration, and locking the cartridge in substantially the shape of a sleeve, the sleeve including at least one axial opening at one of the ends of the sleeve. This is different from the method taught by Garren et al. Thus claim 30 and the claims dependent therefrom are also believed to be in condition for allowance.

Claims 7-8 and 23-24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Garren et al in view of DeVries et al (U.S. 2004/0087976), the Office Action opining that Garren et al discloses all of the claimed limitation but fails to explicitly disclose that a portion of the structure of the cartridge is covered in a coating but that DeVries et al supply the missing teaching.

For a proper rejection of a claim under 35 U.S.C. §103, the cited combination of references must disclose, teach, or suggest all elements/features of the claim at issue. *See, e.g., In re Dow Chemical*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988) and *In re Keller*, 208 U.S.P.Q.2d

871, 881 (C.C.P.A. 1981) (emphasis added).

This rejection is believed to be overcome by the amendments presented herein and the arguments directed to the differences between the present Applicant's device and Garren et al. In addition, claim 7-8 are dependent on now allowable claim 1 and claims 23 and 24 are dependent on now allowable claim 17, making them allowable as a matter of law.

Claims 15-16 have been rejected under 35 U.S.C. § 103(a) over Garren et al in view of Stern (U.S. Patent No. 3,211,152), the Office opining that Garren et al disclose all the claim limitations above but fails to explicitly disclose that the balloon includes at least one second flexible bag of predetermined volume and provided with a second connection means so as to enable it to be connected to a second source of fluid. Stern et al is cited for the missing teachings. In view of the amendments presented herein and the arguments presented hereinabove, this rejection is believed to be overcome and can be withdrawn. In addition, claims 15-16 depend from independent claim 1 which is in condition for allowance.

Claim 32 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Garren et al in view of Campbell et al (U.S. Patent No. 6,984,242).

For a proper rejection of a claim under 35 U.S.C. §103, the cited combination of references must disclose, teach, or suggest all elements/features of the claim at issue. *See, e.g., In re Dow Chemical*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988) and *In re Keller*, 208 U.S.P.Q.2d 871, 881 (C.C.P.A. 1981) (emphasis added).

The Office Action opines that Garren et al disclose the step of inserting the surgical implant in the sleeve but fails to explicitly disclose constraining the surgical implant progressively along its length by means of a jig, but that Campbell supplies the missing teaching, using a jig to reduce the cross-section of the surgical implant while covering the implant in the sleeve in a closed configuration.

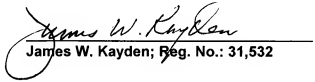
For a proper rejection of a claim under 35 U.S.C. §103, the cited combination of references must disclose, teach, or suggest all elements/features of the claim at issue. *See, e.g., In re Dow Chemical*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988) and *In re Keller*, 208 U.S.P.Q.2d 871, 881 (C.C.P.A. 1981) (emphasis added).

In view of the amendments to claim 30 and the arguments presented hereinabove with respect to the differences between the method of claim 30 and the Garren et al reference, it is believed that this rejection can now be withdrawn and that claim 32 is also in condition for allowance. In addition, claim 32 depends from now allowable claim 30 and is therefore in condition for allowance as a matter of law.

CONCLUSION

With the amendments presented herein, it is believed that all the claims remaining in the Application are in condition for allowance. Early and favorable action in this regarding is hereby respectfully requested. Should there be any minor informalities remaining, the Examiner is respectfully requested to call the undersigned attorney so that this case may be passed to issue at an early date.

Respectfully submitted,



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